Remarks

Claims 1-3, 5-11, and 37 were pending; claim 1 is amended herein; and claims 2-3, 5-11, and 37 are canceled. As a result, claim 1 is pending.

The amendments to the claims are supported throughout the originally filed specification and claims. Amended claim 1 is supported, e.g., by originally filed claim 1, Table 21, SEQ ID NO:162, and at page 31, lines 5-14 and 21-25.

Telephonic Conference

Applicants' attorney thanks the Examiner for the courtesy of a telephonic conference on May 31, 2007. The participants in the telephonic conference were Applicants' attorney Hugh McTavish, Examiner Peter Reddig, and Examiner Susan Unger. In the telephonic conference, the outstanding rejections and possible claim amendments to overcome the rejections were discussed.

The Rejection of the Claims under 35 U.S.C. § 112, Second Paragraph

Claims 10 and 11 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 10 and 11 are canceled herein, obviating this rejection.

The Rejection of the Claims under 35 U.S.C. § 112, First Paragraph

Claims 1-3 and 5-11 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking an adequate written description in the specification. This rejection is respectfully traversed.

The Examiner stated that there was no clear support in the specification for the specific multiple repeat domain of residues 3200 to 3355 of SEQ ID NO:162 (page 3 of the Office Action). The phrase "a multiple repeat domain comprising residues 3200 to 3355 of SEQ ID NO: 162" has been deleted from claim 1, obviating this basis for the rejection. A polypeptide comprising SEQ ID NO:162 is specifically supported, e.g., by Table 21 and SEQ ID NO:162.

The Examiner stated as a second basis for the rejection that in the previous claim 1, the amino acid composition and length between the domains (a), (b), and (c) is not limited. This basis for the rejection is obviated because amended claim 1 does not recite domains (a), (b), and (c) and does not allow for additional amino acids within SEQ ID NO:162 between different domains. Claim 1 recites an isolated recombinant polypeptide comprising a single sequence that Applicants were in possession of.

Next, the Examiner raised in the Office Action as a basis for the rejection a statement in the specification. The specification states:

> Currently, the repetitive units of the repeat domain of the CA125 molecule constitute the majority of its extracellular molecular structure. These sequences have been presented in a tandem fashion based on overlap sequencing data. Some sequences may be incorrectly placed and some repeat units may not as yet be identified (Table 21). (Page 23, lines 24-27.)

In response to this, the Examiner stated "one of skill in the art would not be able to determine what Applicant was in possession of at the time the invention was made given that the molecule encompasses a multiple repeat domain that encompasses unidentified repeat units." (Page 11 of the Office Action.) The amended claim 1 does not encompass unidentified repeat units. It encompasses a single sequence, SEQ ID NO:162, with only the repeat units found in SEQ ID NO:162 in order.

With this Amendment and Response, Applicants have included a Rule 132 Declaration from the lead inventor, Timothy J. O'Brien, in which Dr. O'Brien declares,

> 4. My co-inventors and I have sequenced the cDNA encoding CA125 by cloning and sequencing amplified cDNA fragments encoding portions of CA125, as is described in this patent application. We have aligned overlapping contiguous sequences to determine the overall sequence of the very long CA125 cDNA and the encoded CA125 polypeptide.
>
> 5. We were able to determine overlapping sequences of all portions of the reported CA125 cDNA sequence. Because of the overlapping sequences of the cDNA fragments, we were able to align the fragments in order to assemble the CA125 sequence reported as SEQ ID NO:162. Because of the confirmation provided by overlapping sequences, we have a high degree of confidence that SEQ ID NO:162 is a correct protein sequence of CA125 over the entire length of SEQ ID NO:162. We feel we have taken all steps reasonably possible to verify that SEQ ID NO:162 is correct.

> 6. Since filing the application, we have cloned and sequenced other CA125 cDNA fragments from both normal and cancerous ovarian tissue samples. All of these newer CA125 cDNA sequences are consistent with SEQ ID NO:162, and none of the newer sequences changes our conclusion that SEQ ID NO:162 is a correct protein sequence for CA125.

Thus, the Specification states that SEQ ID NO:162 is a sequence of CA125, and Dr. O'Brien confirms that SEQ ID NO:162 is confirmed by overlapping sequences and that they have taken all steps reasonably possible to confirm the sequence and have a high degree of confidence that it is correct. He also states subsequent research is consistent with the conclusion that SEQ ID NO:162 is a correct sequence of CA125 over the whole length of SEQ ID NO:162.

The specification discloses only a possibility that there are additional repeat units or that the order of repeat units might vary from that of SEQ ID NO:162. Even if that stated possibility were to be a reality, the N-terminal domain of CA125 within SEQ ID NO:162 would still be correct, the C-terminal domain of CA125 within SEQ ID NO:162 would still be correct, and each of the multiple repeat units found in SEQ ID NO:162 would be correct sequence of a multiple repeat unit of SEQ ID NO:162. Thus, the specification and Dr. O'Brien's declaration both indicate that SEQ ID NO:162 contains only CA125 sequence. As such, even if SEQ ID NO:162 were not a correct contiguous sequence of human CA125, a polypeptide comprising SEQ ID NO:162 would still be useful, for instance, to raise antibodies that specifically recognize CA125. But Dr. O'Brien declares, the specification states, and all evidence indicates that SEQ ID NO:162 is a correct contiguous sequence of human CA125.

Applicants were in possession of a recombinant polypeptide comprising SEQ ID NO:162, as recited in claim 1, at the time of filing the application. The specification discloses that SEQ ID NO:162 is a CA125 polypeptide and all evidence still indicates that is true. A recombinant polypeptide comprising SEQ ID NO:162 has utility, e.g., to raise antibodies that specifically recognize CA125. Accordingly, claim 1 complies with the written description requirement of 35 U.S.C. § 112, first paragraph.

Thus, withdrawal of the rejection of claim 1 under the written description requirement of 35 U.S.C. § 112, first paragraph, is respectfully requested.

Objection to the Specification

The Examiner stated that disclosure is objected to "because of the sequence of SEQ ID NO:150 contains sequence errors and does not represent a multiple repeat unit of the invention" (*sic*). And "appropriate correction is required."

In reply, Applicants point out that SEQ ID NO:150 does not contain sequence errors. SEQ ID NO:150 is the sequence that was expressed as described in page 17, line 19 to page 18, line 4, by PCR amplifying DNA encoding a multiple repeat unit from ovarian tumor cDNA and ligating the PCR amplified fragment into an expression vector. And SEQ ID NO:150 does "represent a multiple repeat unit of the invention" in that the first 153 amino acids of SEQ ID NO:150 are the first 153 amino acids of a 156-amino-acid repeat unit. This makes it suitable to express SEQ ID NO:150 as described in the specification in order to characterize it by showing by Western blotting that antibodies against CA125 recognized the SEQ ID NO:150 recombinant polypeptide (page 18, lines 16-23 and FIG. 4).

Thus, Applicants believe the specification contains no errors in need of correction. If the Examiner believes certain lines of the specification are in error and require correction, Applicants request that the Examiner point to those lines specifically and suggest the appropriate correction the Examiner desires rather than making a vague statement that appropriate correction of the specification is required, which does not give Applicant sufficient guidance to comply. Applicants also request that the Examiner point to the authority in the statutes or regulations for requiring correction, since none was cited.

Conclusion

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (651-207-8270) to facilitate prosecution of this application.

Respectfully submitted,

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By their Representatives,

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Date 6/20/2007 By: Hugh McTavish

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient first class postage, in an envelope addressed to: Mail Stop Amendement, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 20 day of June 2007.

Hugh McTavish
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